

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problem Mailbox.**

OCTOBER, 1997 VOLUME 11 NUMBER 7

JOT

Lippincott - Raven

P U B L I S H E R S

JOURNAL OF ORTHOPAEDIC TRAUMA

OFFICIAL JOURNAL OF

The Orthopaedic Trauma Association

The International Society for Fracture Repair

The Belgian Orthopaedic Trauma Association

Distal Femoral Fixation: A Biomechanical Comparison of the Standard Condylar Buttress Plate, a Locked Buttress Plate, and the 95-Degree Blade Plate

Kenneth J. Koval, James J. Hoehl, Frederick J. Kummer, and Jordan A. Simon

Department of Orthopaedic Surgery, Hospital for Joint Diseases, Orthopaedic Institute, New York, New York, U.S.A.

Objectives: This biomechanical cadaver study was performed to compare the fixation stability of a standard lateral condylar buttress plate with a similar condylar buttress plate with the distal screws locked to the plate. Then the study was repeated with six additional matched femoral pairs to compare the locked plate with a standard 95-degree blade plate.

Design: Six matched pairs of mildly osteopenic femurs were selected, and each side was assigned randomly to fixation with either a standard lateral condylar buttress plate or a modified lateral condylar buttress plate with locked distal screws. The experiment was repeated with six additional matched pairs of femurs instrumented with either a modified lateral condylar buttress plate with locked distal screws or a standard 95-degree blade plate.

Intervention: The femurs were instrumented, and a gap osteotomy was created at the distal femoral metaphysis. The instrumented femurs were then mechanically tested in axial compression and bending/torsional loading to determine fixation stability; then they were loaded at 1,000 newtons for 10³ cycles and retested for stability.

Main Outcome Measurement: The displacement across the osteotomy gap at 100-newton and 1,000-newton axial loads was measured directly for each specimen before and after cycling. In addition, resistance to displacement in bending/torsional loading (newtons/centimeter) was determined from load/displacement curves, before and after cycling.

Results: The locked buttress plate provided significantly greater fixation stability than the standard plate both before and after cycling in axial loading. The locked buttress plate also proved significantly more stable in axial loading than the blade plate both before and after cycling.

Conclusion: A condylar buttress plate with locked screws is a valid concept for improving fixation stability.

Key Words: Biomechanical, Distal femur, Fracture fixation.

Distal femur fractures with loss of the medial buttress present a challenge to the surgeon. Commonly used fixation devices include the blade plate or dynamic condylar screw (5). However, these fixed-angle devices are not suitable for severely comminuted fractures of the femoral condyles. In these cases, a lateral buttress plate is indicated. However, if the medial metaphyseal buttress is compromised, the fracture can fall into varus before healing. Sanders et al. (6) have recommended double-plating techniques for fixation of these difficult fractures. Although these authors have had good results with the double-plating technique, the surgery requires disruption of the medial and lateral soft tissues to achieve fixation. An alternative method of double-plating

has been presented by Matelic et al. (4) for the treatment of nonunions of distal femoral fractures in which a medial endosteal plate is transfixed with screws placed through the lateral plate. Where the lateral cortex is deficient, Schuller nuts can be used to lock the screw to the lateral plate to augment fixation. The plate used in the current biomechanical study was designed to obviate the need for a second plate by providing a secure locking mechanism in the distal aspect of a single condylar buttress plate, as first proposed by Sanders et al. (6). Locking the screws to the plate facilitates the use of unicortical fixation and, in most cases, causes the plate/screw construct to act as a fixed-angle device. Toggling of the screws within the plate is prevented, thus decreasing the risk of fracture displacement.

To date, no study has been performed to evaluate the biomechanical characteristics of plates with locked screws for fracture fixation. This laboratory study was performed initially to compare fixation stability of a standard condylar buttress plate with the same plate with locked screws in an unstable distal femoral fracture model. Later, the locked plate was compared similarly with a standard 95-degree blade plate.

Accepted June 16, 1997.

Address correspondence and reprint requests to Dr. Kenneth J. Koval, Department of Orthopaedic Surgery, Hospital for Joint Diseases, Orthopaedic Institute, 301 East 17th Street, New York, NY 10003, U.S.A.

No financial support of this project has occurred. The authors have received nothing of value.

This manuscript does not contain information about medical devices.

MATERIALS AND METHODS

Twenty matched pairs of embalmed, human femora were obtained and evaluated by biplanar radiographs and dual-energy x-ray absorption scanning (QDR-2000 Supine Lateral X-Ray Bone Densitometer, Hologic, Waltham, MA, U.S.A.). Screening was performed to exclude those specimens with pathologic lesions. Twelve matched pairs of mildly to moderately osteoporotic femurs (bone density 0.350–0.675 gram/centimeter²) were selected for inclusion in this study. Paired Student's *t* tests were performed to ensure that there were no significant differences between instrumentation groups (Table 1).

The femurs were mounted in proximal and distal holding fixtures using an alignment jig with acrylic cement so that the centers of the femoral head and the intercondylar notch were located over the central axes of these fixtures, resulting in 12- to 15-degree shaft varus. Initially, six matched femoral pairs were assigned randomly to one of two methods of instrumentation: (a) a standard six-hole lateral condylar buttress plate (Synthes, Paoli, PA, U.S.A.) using four distal 6.5-millimeter cancellous screws placed in a pattern to maximize screw length within the bone and prevent the screws from interfering with each other, or (b) a modified lateral condylar buttress plate made by welding four tapped nuts (Richards Part #A390000, Memphis, TN, U.S.A.) into the screw holes of the distal plate flange in the identical pattern used for the standard buttress plate (Fig. 1) to create a locked screw system. Four 4.5-millimeter cortical screws of similar length to the 6.5-millimeter screws used for the standard buttress fixation were inserted through the nuts into the femoral condyles. For both types of instrumentation, three 4.5-millimeter cortical screws were used proximally to secure the plate to the femoral shaft. After instrumentation, a one-centimeter section of bone was removed creating a gap, beginning six centimeters proximal to the lateral joint line using a thin-blade reciprocating saw.

The bone/implant constructs were mounted on a Material Testing System 410 servohydraulic testing machine (MTS Systems Inc., Minneapolis, MN, U.S.A.) (Fig. 2). An axial preload of 100 newtons was applied to the femoral head to stabilize the construct. Then an axial compressive load of 1,000 newtons was applied to the femoral head at a rate of 100 newtons/second. Displacement from the initial position of the gap to the 100-newton preload was measured with a caliper at its medial aspect. Gap displacement from the preload to the maximum load was measured continuously using an electronic displacement gauge (IDC-25E, Mitutoyo Co., Tokyo, Japan) attached medially across the one-centimeter gap.

The specimens also were tested in a bending/torsional mode to simulate the femoral loads produced in rising from a seated position (1). A 500-newton load was applied to the femoral head in an anterior-to-posterior direction, with the femoral shaft and neck held parallel to the testing platform. The femoral fixture was

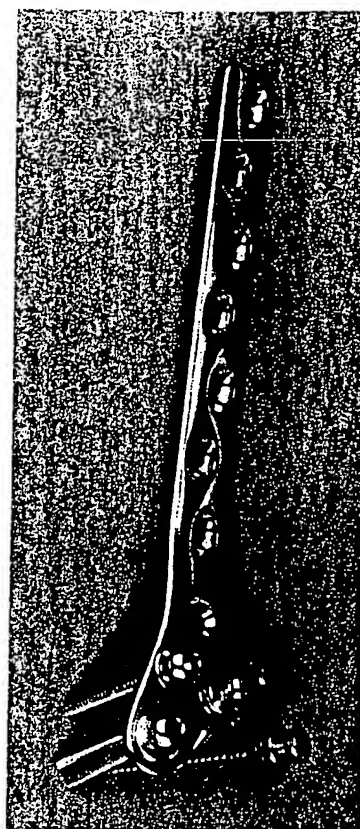


FIG. 1. The locked condylar buttress plate and the pattern of the four locked 4.5-millimeter cortical screws. Note the flange of the threaded nuts is welded into the distal screw holes.

held in a vise, and the femur was supported at the level of the lesser trochanter by a steel block to minimize posterior bending of the femoral shaft. Thus, as load was applied to the femoral head, a torsional moment was imposed across the gap. Fixation stability in this testing mode was defined as the average slope of load-deflection curves, normalized for neck length.

Then the femurs were subjected to an axial cyclic load of 1,000 newtons for 10⁵ cycles (three hertz) to approximate loading in the initial healing period. Load-deflection curves and fracture displacements in axial loading and bending/torsion were acquired again to determine the stability of the constructs post-cycling.

The experiment was repeated with six additional matched femoral pairs to compare stability of the locked plate with a standard 95-degree blade plate (Synthes, Paoli, PA, U.S.A.) with one additional 6.5-millimeter distal cancellous screw inserted into the distal fragment. The testing protocol was identical to the previous comparison.

Statistical analysis of the stiffness and displacement values of the paired specimens was performed using Student's *t* tests. A *p* value of less than 0.01 was considered statistically significant.

RESULTS

There was no statistical difference in bone density between the specimens instrumented with the locked buttress plate versus the standard buttress plate or with the locked plate versus the 95-degree blade plate (Table 1).

TABLE 1. Bone density values for selected specimens

Fixation group	Mean bone density (g/cm ³)	SD
Standard buttress plate	0.521	0.147
Locked buttress plate	0.533	0.157
<i>p</i> = 0.256		
Blade plate	0.496	0.205
Locked buttress plate	0.465	0.134
<i>p</i> = 0.200		

SD, standard deviation.

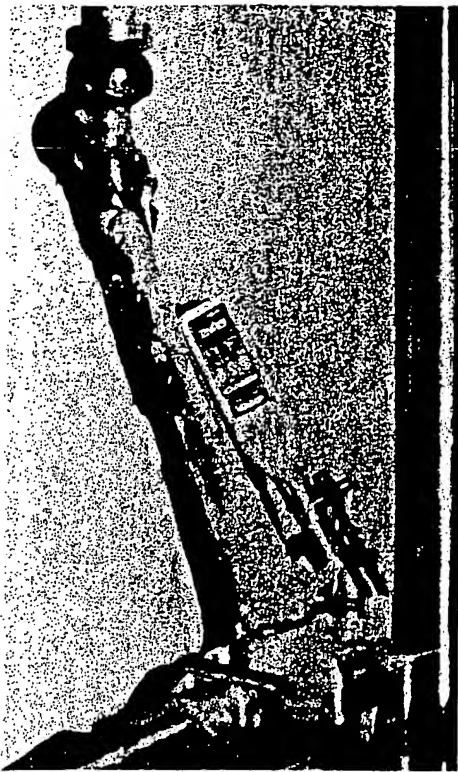


FIG. 2. An instrumented femur mounted on an MTS testing machine for axial loading; displacement gauge is located across the medial aspect of the gap.

Table 2 gives the maximum fracture displacements measured in axial loading at the preload of 100 newtons and at the maximum testing load of 1,000 newtons for both the standard and locked condylar buttress plate constructs. The data presented are average values for the six femurs tested with each method of fixation. In all cases, a disproportionate amount of motion occurred during the 100-newton preload, particularly for the standard condylar buttress plate. The locked plate construct was significantly more stable (i.e., smaller displacement at a given load) to axial loading than the standard plate construct both before and after cyclic loading.

Table 3 compares the fracture displacement of the locked buttress plate to a 95-degree blade plate in axial loading. The locked buttress plate construct was significantly more stable to axial displacement at the 1,000-newton load both before and after cyclic loading.

TABLE 2. Comparison of axial stability for locked and standard plates

	Precycling		Postcycling	
	100 N	1,000 N	100 N	1,000 N
Locked plate	0.26 (0.17)	1.34 (0.70)	0.41 (0.27)	1.52 (0.87)
Standard plate	0.78 (0.9)	3.48 (1.70)*	1.27 (1.10)	4.30 (2.25)*

Values are displacement of gap in millimeters (standard deviation). N, newtons. *Significant difference between plates at $p < 0.01$.

Table 4 shows the resistance to bending/torsional loading for the three plates expressed as newtons/centimeter. Although the locked plate was consistently more resistant to bending/torsional loading compared with both the standard buttress and blade plate, these differences were not statistically significant because of their large standard deviations.

DISCUSSION

In this study, the locked condylar buttress plate demonstrated significantly more stable fixation than the standard buttress plate or the 95-degree condylar blade plate for a distal femoral gap osteotomy model. The displacement measured for a 1,000-newton axial load was significantly smaller for the locked plate both before and after cyclic loading compared with the standard buttress and 95-degree blade plates.

The standard deviations in axial displacement for the standard condylar buttress and blade plates are larger than those of the locked buttress plate. The distal fragment of five of the standard buttress plate and three of the blade plate specimens exhibited gross loosening, especially after cycling. Gross loosening in the group fixed with the standard buttress plate was caused by partial pull-out of the screws from the condyles and toggling motion at the screw plate junction. The blade plates appeared to loosen due to a windshield wiper effect of the blade within the condyles. The locked condylar buttress plate did not exhibit loss of distal fixation in any specimen, and thus, the standard deviation of displacement values both before and after cyclic loading was smaller in comparison with the other two fixation methods.

Analysis of the data obtained for bending/torsional loading did not show statistically significant differences between the different types of instrumentation, although the resistance to bending/torsional loading for the locked condylar buttress plate was approximately 50 percent greater than both the standard buttress and blade plates.

The increased stability of the locked condylar buttress plate as compared with the standard condylar buttress plate can be attributed to the absence of toggling motion at the screw/plate interface. None of the locked plates exhibited visible loosening at this interface after axial cycling, nor was there significant gross displacement during the axial preload. Gross displacement of the distal fragment during preload was observed in the standard condylar buttress fixation, with the majority of the relative motion occurring at the screw/plate

TABLE 3. Comparison of axial stability for locked and blade plates

	Precycling		Postcycling	
	100 N	1,000 N	100 N	1,000 N
Locked plate	0.21 (0.09)	1.42 (0.65)	0.35 (0.18)	1.60 (0.85)
Blade plate	0.55 (0.21)	3.2 (1.80)*	0.93 (0.43)*	3.65 (2.05)*

Values are displacement of gap in millimeters (standard deviation). N, newtons. *Significant difference between plates at $p < 0.01$.

TABLE 4. Comparison of plate stability in bending/torsional loading

	Precycling	Postcycling
Locked plate	716 (358)	661 (394)
Standard plate	497 (332)	427 (299)
Locked plate	635 (338)	568 (342)
Blade plate	445 (244)	412 (283)

Values are resistance to displacement in newtons/centimeter (standard deviation).

interface as opposed to the bone/screw interface in the distal fragment. By locking the screws to the plate, this toggling motion was eliminated, allowing only minimal motion at the bone/screw interface, which led to a significantly more stable construct.

The increased stability of the locked condylar buttress plate compared with the blade plate cannot be attributed to a lack of distal screw toggling because both of these devices essentially are fixed-angle devices. However, the 95-degree blade plate achieves fixation of the distal fragment from its blade inserted into a single area of the distal fragment and one screw inserted in an oblique fashion. Any widening of the blade channel in the bone during insertion or due to compacting of the osteopenic cancellous bone on loading will lead to motion at the blade/bone interface. The locked plate achieves its purchase by its screws being distributed in a more dispersed region of bone which, in this study, led to a more stable construct. However, the blade plates did show more stability than the standard plates, although this was not a matched-pair comparison.

Although this study illustrates the mechanical behavior of these constructs in vitro, it does have several limitations. The femurs used were embalmed specimens. However, studies have shown no significant differences in strength between embalmed and fresh bone (2). Also, in previous studies using both transverse and gap distal femur osteotomies, stiffness values recorded from the gap model were significantly less than those in the compressed transverse model, regardless of the fixation device or testing mode (3). The transverse osteotomy model probably would not show the same significant differences between the three constructs tested because of its inherent stability (e.g., bone contact and load sharing).

A limitation of the locked-plate concept is that the locked screws are set in a fixed orientation and cannot be arranged to accommodate different conformations. Because the plate used in this study was a prototype, one pattern was used for placement of the threaded holes. In all the specimens used in this study, the fixed orientation of the screws within the femoral condyles did not result in intraarticular penetration of the screws. In the clinical setting, where an intercondylar fracture may be present, there remain two holes without inserts for the introduction of standard lag screws. All six of the distal screws of the standard plate can be adjusted to

accommodate different angles that may be beneficial for comminuted fractures, yet any significant load-bearing will result in a toggle effect, as shown in the present study. In this study, a plate bender was used to contour the buttress plates to conform to the distal femoral condyle, which is a standard technique for plate instrumentation. However, bending of a locked plate with unreinforced tapped holes could distort the screw holes and prevent screw insertion. Placement of threaded inserts before bending could prevent this distortion. The locked plate used in this study actually had welded, built-up threaded inserts that did not distort during contouring. An alternative design for this plate could have used Schuhli nuts placed between the plate and bone distally. However, the use of Schuhli nuts would have required machining of the round distal flange holes to an oblong shape to mimic the holes in a dynamic compression plate. In addition, the welded insert design provided intimate contact of the plate flange to the lateral bone surface. Schuhli nuts would elevate the plate away from the bone, which in the clinical situation could lead to soft tissue irritation. Four-and-a-half-millimeter cortical screws were used for the locked plate because locked nuts were not available to accommodate 6.5-millimeter cancellous screws. The locked plate creates large forces at the screw-plate junction, which could be a site of fatigue failure. Fully threaded 6.5-millimeter cancellous screws should provide an improved purchase within the condyles and a greater resistance to fatigue failure at screw-plate junction because of their larger root diameters. No fatigue failure was seen in this study with axial cycling loads of 1,000 newtons for 100,000 cycles.

In this study, the locked condylar buttress plate provided significantly greater fixation stability than both a standard buttress plate and 95-degree blade plate in a distal femoral gap osteotomy model. These results show that a condylar buttress plate using locked screws is a valid concept to maximize fixation stability in osteopenic distal femur fractures.

REFERENCES

1. Davy DT, Kotzar GM, Brown RH, et al. Telemetric force measurements across the hip after total arthroplasty. *J Bone Joint Surg* 1988; 70A:45-50.
2. Evans FG. *Mechanical properties of bone*. Springfield, IL, Charles C. Thomas, 1973, pp 241-243.
3. Koval KJ, Kummer FJ, Bharam S, Chen D, Halder S. Distal femoral fixation: a laboratory comparison of the 95° plate, antegrade and retrograde inserted reamed intramedullary nails. *J Orthop Trauma* 1996; 10:378-382.
4. Matelic TM, Monroe MT, Mast JW. The use of endosteal substitution in the treatment of recalcitrant nonunions of the femur: report of seven cases. *J Orthop Trauma* 1996;10:1-6.
5. Sanders R, Regazzoni P, Ruedi T. Treatment of supracondylar-intracondylar fractures of the femur using the dynamic condylar screw. *J Orthop Trauma* 1989;3:214-222.
6. Sanders R, Swiontkowski M, Rosen H, Helfet D. Double-plating of comminuted, unstable fractures of the distal part of the femur. *J Bone Joint Surg* 1991;3:341-346.